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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,818	06/18/2001	James F. McGuckin JR.	1243	2564

7590

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EXAMINER

PHANIJPHAND, GWEN G

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 10/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/883,818

Applicant(s)

MCGUCKIN ET AL.

Examiner

Gwen Phanijphand

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 14-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

- I. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1 through 13, drawn to a vessel filter apparatus, classified in class 606, subclass 200.
 - II. Claims 14 through 18, drawn to a method of implanting a vein filter, classified in class 604, subclass 93.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as an apparatus and method of using the apparatus. The inventions are distinct if it can be shown that either (1) the apparatus as claimed can be used by another method or inserted by another device, or (2) the method of using the apparatus can be used by a different apparatus. In this case, the method as claimed can be used for inserting a different apparatus, where saline is needed.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Neil Gershon on 9/24/02 a provisional election was made without traverse to prosecute the invention of James McGuckin, Jr. et al., U.S. Application No. 09883818, claims 1-18. Affirmation of this election must be made by applicant in replying to this Office action. The vessel filter apparatus, which read on claims 1-13, was chosen for reviewing out of the restricted claims.

Claim Rejections – 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 2, 4, and 7-13 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,370,657 to Irie.

Regarding claim 1, Irie discloses in Fig. 4 a vessel filter comprising a first filtering portion (left 22) and a first anchoring portion (left 23) and that the transverse dimension of first filtering portion in an expanded configuration being less than the transverse dimension of the first anchoring portion in an expanded configuration. Irie also discloses a second filtering portion (right 22) and a second anchoring portion (right 22), and transverse dimension of the second filtering portion being less than a transverse dimension of the second anchoring portion. Irie discloses that the first and second filtering portions are positioned closer to each other than the first and second anchoring portions, and the anchoring portions being formed on first and second opposite portions of the vessel filter.

Regarding claim 2, Irie discloses in Fig. 4 a sleeve (28) positioned between the first and second filtering portions.

Regarding claim 7, Irie discloses in Fig. 4 the transverse dimensions of the first and second anchoring portions and filtering portions being substantially equal.

Regarding claim 8, Irie discloses in Fig. 4 the filtering portions (22 on each side) progressively increasing in diameter towards its respective anchoring portion.

Art Unit: 3731

Regarding claim 9, Irie discloses in Fig. 4 a vessel filter having a first portion (22, 23 on left), a second portion (22, 23 on right) and an intermediate portion (28) between the first and second portions. Irie discloses the first portion increasing in diameter from the intermediate portion, and the second portion increasing in diameter from the intermediate portion. Irie also discloses a region closer to the intermediate portion forming a filter portion (22).

Regarding claim 10, Irie discloses in Fig. 4 a filter (22) formed by each wire (22, 23, 28) forming a first, second, and intermediate portions.

Regarding claim 11, Irie discloses in Fig. 4 a retaining sleeve (28) at the intermediate portion retaining a wire.

Regarding claim 13, Irie discloses the filter being composed of shape memory metal (col. 3, ll. 66-68).

2. Claims 1, 2, 4, and 7-13 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 5,746,767 to Smith.

Regarding claim 1, Smith discloses in Fig. 2 a vessel filter comprising a first filtering (left portion of 16, closer to the center) and anchoring portions (left end portion of 16) and that the transverse dimension of first filtering portion in an expanded configuration being less than the transverse dimension of the first anchoring portion in an expanded configuration. Smith also discloses a second filtering (right portion of 16, closer to the center) and anchoring portions (right end of 16), and the transverse dimension of the second filtering portion being less than a transverse dimension of the second anchoring portion. Smith discloses that the first and second filtering portions (left and right portions of 16 closer to the center) are positioned closer to each

Art Unit: 3731

other than the first and second anchoring portions (left and right end portions of 16), and the anchoring portions being formed on first and second opposite portions of the vessel filter.

Regarding claim 2, Smith discloses in Fig. 1 a sleeve (26) positioned between the first and second filtering portions (16).

Regarding claim 4, Smith discloses in Fig. 2 a first anchoring member (left 18) extending from the first anchoring portion (left 16) and a second anchoring member (right 18) extending from a second anchoring portion (right 18).

Regarding claim 7, Smith discloses in Fig. 2 the transverse dimensions of the first and second anchoring portions (16) and filtering portions (16) being substantially equal.

Regarding claim 8, Smith discloses in Fig. 2 the filtering portions (16) progressively increasing in diameter towards its respective anchoring portion.

Regarding claim 9, Smith discloses in Fig. 2 a vessel filter having a first portion (left portion of 16), a second portion (right portion of 16) and an intermediate portion (26) between the first and second portions. In Fig. 2, Smith shows the first portion increasing in diameter from the intermediate portion, and the second portion increasing in diameter from the intermediate portion. Smith also discloses in Fig. 2 the region closer to the intermediate portion forming a filter portion.

Regarding claim 10, Smith discloses in Fig. 1 a filter formed by each wire forming a first (left portion of 16), second (right portion of 16), and intermediate portions (26).

Regarding claim 11, Smith discloses in Fig. 1 a retaining sleeve (26) at the intermediate portion retaining a wire (claim 9).

Art Unit: 3731

Regarding claim 12, Smith discloses in Fig. 2 a tubular anchoring member (18) extending from the first and second portions (left and right portions of 16) and engaging the vessel wall (col. 3, ll.20-21).

Regarding claim 13, Smith discloses the filter being composed of shape memory metal (col. 3, ll. 22-24).

3. Claims 1-14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by U.S. Patent No. 6,251,122 B1 to Tsukernik.

Regarding claim 1, Tsukernik discloses a vessel filter in Fig. 3 comprising a first filtering portion (32) and a first anchoring portion (36) and that the transverse dimension of first filtering portion in an expanded configuration being less than the transverse dimension of the first anchoring portion in an expanded configuration. Tsukernik also discloses a second filtering portion (42) and a second anchoring portion (46), and the transverse dimension of the second filtering portion being less than a transverse dimension of the second anchoring portion. Tsukernik further shows in Fig. 3 that the first and second filtering portions are positioned closer to each other than the first and second anchoring portions, and the anchoring portions (36, 46) being formed on first and second opposite portions of the vessel filter (32, 42).

Regarding claim 2, Tsukernik discloses a sleeve positioned between the first and second filtering portions (Fig. 3, 72, 74).

Regarding claim 3, Tsukernik shows in Fig. 3 the filtering and anchoring portions formed by three wires. The first filtering and anchoring portions are formed by the three wires: 32, 36 (first wire); 30 (second wire); and 72, 76 (third wire). The second filtering and anchoring

Art Unit: 3731

portions are formed by the three wires: 42, 46 (first wire); 40 (second wire); and 74, 78 (third wire).

Regarding claim 4, Tsukernik discloses in Fig. 3 a first anchoring member (60) extending from the first anchoring portion (30) and a second anchoring member (62) extending from a second anchoring portion (42).

Regarding claim 5, Tsukernik discloses in Fig. 3 the first and second filtering and anchoring portions formed by three wires, each having a lumen to receive one of the three wires (72), and each further having first and second opposing sharpened ends (60, 62) for engaging the vessel wall.

Regarding claim 6, Tsukernik discloses a collapsed filter and three wires in an elongated configuration substantially parallel to a longitudinal axis of the filter (col. 3, ll.3-11).

Regarding claim 7, Tsukernik discloses in Fig. 3 the transverse dimensions of the first and second anchoring portions and filtering portions being substantially equal.

Regarding claim 8, Tsukernik discloses in Fig. 3 the filtering portions progressively increasing in diameter towards its respective anchoring portion.

Regarding claim 9 Tsukernik discloses in Fig. 3 a vessel filter having a first portion (30, 32, 36, 76), a second portion (40, 42, 46, 78), and an intermediate portion (50, 72, 74) between the first and second portions. Tsukernik also discloses in Fig. 3 the first and second portions increasing in diameter from the intermediate portion. Tsukernik further discloses the region closer to the intermediate portion forming a filter portion (34, 44).

Regarding claim 10, Tsukernik discloses in Fig. 3 a filter formed by each wire forming a first (30, 32, 36, 76), second (40, 42, 46, 78), and intermediate portions (50, 72, 74).

Art Unit: 3731

Regarding claim 11, Tsukernik discloses in Fig. 3 a retaining sleeve (72, 72) at the intermediate portion retaining a wire.

Regarding claim 12, Tsukernik discloses in Fig. 3 a member (60, 62) extending from the first and second portions to engage the vessel wall.

Regarding claim 13, Tsukernik discloses the filter being composed of shape memory metal (col. 5, ll. 23-24).

Claim Rejections – 35 U.S.C. 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,746,767 to Smith.

Regarding claims 3, 5, and 6, Smith discloses filtering and anchoring portions with a lumen to receive the wires and ends on each for engaging the vessel wall, and a collapsed filter with wires parallel (col. 3, ll. 11-17) to the longitudinal axis of the filter, but Smith does not show that the portions are formed by three wires. In col. 4, ll. 34-39, Smith does disclose that fewer struts may be used. The number of wires or struts affects the size and number of emboli captured by the filter, and thus, it is subjective to the user to choose the most advantageous number of struts for a surgical area and procedure. It is obvious to one of ordinary skill in the art

Art Unit: 3731

at the time of the invention to use three struts and well known that using three struts on the filter of Smith can be most effective for capturing emboli.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,634,942 to Chevillon et al.

U.S. Patent No. 5,976,172 to Homsma et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gwen Phanijphand whose telephone number is 703-305-4845.


The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

GP
September 30, 2002

Gwen Phanijphand
Patent Examiner
Art Unit 3731


Michael J. Milano
Supervisory Patent Examiner
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